Express Mail Label No.: EL451220426US

NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity) *(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*	Docket No. S63.2-8606
	Total Pages in this Submission *(including checks and postcard)* 56

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled: IMPROVED TISSUE SUPPORTING DEVICES

and invented by: Paul H. Burmeister, Charles L. Euteneuer, Brian J. Euteneuer, Brian J. Brown, Paul J. Fordenbacher, Anthony C. Vrba

If a CONTINUATION APPLICATION, *check appropriate box and supply the requisite information:*
☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: 08/737,492, filed 11-18-96 which is a National Stage Application based on PCT/US95/06228 filed May 18, 1995 which is a Continuation-in-Part of U.S. Application No. 08/246,320 filed May 19, 1994, now abandoned.

Enclosed (in addition to the 4 pages of this transmittal) are: **4 pages**

Application Elements

1. ☒ **Filing fee as calculated below:**
   a. ☐ **filing fee is NOT ENCLOSED - fee will be paid at the time of responding to the Notice of Missing Parts -- DO NOT CHARGE DEPOSIT ACCOUNT**
   b. ☒ **a check in the amount of $760.00 to cover the filing fee is enclosed.** **1 pages**
   c. ☐ **charge to Deposit Account as authorized at Item 2(a) on next page.**

FEE CALCULATION AND C L A I M S					
For	**No. Filed**	**No. Allowed**	**No. Extra**	**Rate**	**Fee**
Total Claims	14	- 20 =	0	x $18.00	$ 0.00
Indep. Claims	1	- 3 =	0	x $78.00	$ 0.00
				BASIC FEE	$760.00
				TOTAL FILING FEE	$760.00

continued on next page.....

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2. **The Commissioner is hereby authorized to charge and credit Deposit Account No. 22-0350 as described below. A duplicate copy of this sheet is enclosed.**
   - a. ☐ **Charge the amount of $____ as filing fee.**
   - b. ☒ **Credit any overpayment.**
   - c. ☒ **Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.**
   - d. ☐ **Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).**

3. ☒ Specification having 21 pages and including the following: 21 pages
   - a. ☒ Application Cover Sheet - 1 page
   - b. ☒ Descriptive Title of the Invention -
   - c. ☐ Cross References to Related Applications *(if applicable)*
   - d. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
   - e. ☐ Reference to Microfiche Appendix *(if applicable)*
   - f. ☒ Background of the Invention
   - g. ☒ Brief Summary of the Invention
   - h. ☒ Brief Description of the Drawings *(if applicable)*
   - i. ☒ Detailed Description
   - j. ☒ Claim(s) as Classified Below - 5 pages
   - k. ☒ Abstract of the Disclosure -1 page

4. ☒ Drawing(s) *(when necessary as prescribed by 35 U.S.C. 113)* 13 sheets 13 pages

5. ☒ Oath or Declaration - 3 pages
   - a. ☐ Newly executed *(original or copy)* ☐ Unexecuted
   - b. ☒ Copy from a prior application (37 C.F.R. 1.63(d)) *(for continuation/divisional application only)*

6. ☒ Separate Power of Attorney ___ pages

   ☐ 37 C.F.R. 3.73(B) Statement *(when there is an assignee and power of attorney is from assignee)*. It is hereby certified that the undersigned has authority to make this certification and has reviewed all the documents in the chain of title of the patent application identified herein and, to the best of undersigned's knowledge and belief, title is in the assignee identified in the accompanying Power of Attorney.

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☐ Power of Attorney filed in parent application.

7. ☒ Incorporation by Reference *(usable if Box 5b is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 5b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

8. ☐ Computer Program in Microfiche *(Appendix)* ___ pages

9. ☐ Nucleotide and/or Amino Acid Sequence Submission ___ pages
(if applicable, all must be included)
   a. ☐ Paper Copy
   b. ☐ Computer Readable Copy *(identical to computer copy)*
   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

10. ☐ Assignment Papers: ___ pages
   a. ☐ Assignment Recordation Cover Sheet (Form PTO 1595)
   b. ☐ Assignment
   c. ☐ A check in the amount of $___ to cover the Recordal Fee
   d. ☐ Previously recorded on_____, Reel *, Frame *

11. ☐ English Translation Document *(if applicable)* ___ pages

12. ☐ Information Disclosure Statement: ___ pages
   a. ☐ PTO Form 1449 b. ☐ Copies of IDS Citations

13. ☒ Preliminary Amendment 11 pages

14. ☒ Acknowledgement Postcard 1 page

15. ☒ Form of Mailing - Express Mail *(Specify Label No.)*: EL451220426US

16. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)* ___ pages

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NEW UTILITY PATENT APPLICATION TRANSMITTAL **(Large Entity)** *(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*	Docket No. S63.2-8606
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17. ☒ Additional Enclosures *(please identify below)*: 2 pages
- ☒ Constructive Petition for Extension of Time and Fee Authorization Pursuant to 37 C.F.R. §1.136(a)(3) - 1 page
- ☒ Change of Address of Law Firm - 1 page

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: October 26, 1999

By: _____
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Paul H. Burmeister et al.
Application No.:	*(Not yet assigned)*
Filed:	October 26, 1999
For:	IMPROVED TISSUE SUPPORTING DEVICES
Examiner:	*(Not yet assigned)*
Group Art Unit:	*(Not yet assigned)*

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-8606

PRELIMINARY AMENDMENT

Before beginning examination and calculating the fees in this application, please amend the above-identified application as indicated below:

In the Specification:

Please amend the specification as follows:

Cross-reference to Related Applications

This application is a Continuation of US Application 08/737,492, filed November 18, 1996 which is a National Stage Application based on PCT/US95/06228 filed May 18, 1995 which is a Continuation-in-Part of U.S. Application No. 08/246,320 filed May 19, 1994, now abandoned. All of the applications referred to in this paragraph are incorporated herein in their entirety by reference.

In the Claims:

Please cancel claims 1-21.

Please add new claims 22-35 as follows:

--22. A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

23. The stent of claim 22, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.

24. The stent of claim 23, wherein the connecting members are connected to the apices of the adjacent annular members.

25. The stent of claim 23, wherein the plurality of struts comprises left and right struts, with each pair of left and right struts connected to each other at an apex.

26. The stent of claim 23, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state.

27. The stent of claim 23, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.

28. The stent of claim 23, wherein at least one of the annular elements is closed such that the plurality of alternating struts and apices are connected to each other to form a closed annular element.

29. The stent of claim 22, wherein at least one of connecting member has a plurality of alternating segments.

30. The stent of claim 29, wherein the at least one connecting member has a plurality of alternating and angled straight segments.

31. The stent of claim 22, wherein each connecting member has a larger longitudinal dimension when each annular element is in the expanded state than in the compressed state to compensate for the smaller longitudinal dimension of the annular element in the expanded state.

32. The stent of claim 22, wherein each connecting member has a smaller longitudinal dimension when each annular element is in the compressed state than in the expanded state to compensate for the larger longitudinal dimension of the annular element in the compressed state.

33. The stent of claim 22, wherein the stent has a plurality of segments along its length, each segment assuming a different diameter when the annular elements are in their expanded state.

34. The stent of claim 22, wherein the annular elements and connecting members define an alternating longitudinal pattern of annular elements and connecting members.

35. The stent of claim 22 comprising, at about normal body temperatures, a shape-memory, superelastic, austenitic alloy portion and a shape memory, martensitic alloy portion, the superelastic austenitic alloy portion having a transition temperature from martensite to austenite less than body temperature while the martensitic alloy portion has a transition temperature from martensite to austenite greater than body temperature, the martensitic alloy portion and superelastic austenitic alloy portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two alloy portions act in combination to allow, upon transformation of the austenitic alloy portion to martensite at a temperature below the transition temperature, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite alloy portion from martensite back to austenite to self-expand the stent back to about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenitic superelastic

portion, the shape memory of the superelastic austenitic portion tending to form the stent to a larger diameter due to its shape memory but being restrained therefrom by the martensitic alloy portion whereby the austenitic alloy portion can be deformed by external force without plastic deformation along with the martensitic portion to an enlarged stent diameter beyond that of the self-expanded diameter.--

REMARKS

The instant application is a Continuation of US Application 08/737,492, filed November 18, 1996 which is a National Stage Application based on PCT/US95/06228 filed May 18, 1995 which is a Continuation-in-Part of U.S. Application No. 08/246,320 filed May 19, 1994, now abandoned. All of the applications referred to in this paragraph are incorporated herein in their entirety by reference. Applicant notes that prosecution of the parent application, US Application 08/737,492 has been suspended due to a potential interference.

With this Preliminary Amendment, claims 1-21 have been canceled and claims 22-35 have been added to this continuation application. Claims 22-34 have been copied from US 5,827,321 to Roubin, issued October 27, 1998 in accordance with 37 C.F.R. § 1.604 to provoke an interference.

Support for all of the new claims is found in Figs. 11a, 11b and page 2, line 21 of US 08/246,320, the earliest application from which priority is claimed. Further support for new claim 35 is found, *inter alia*, in claim 9 as filed of US 08/246,320 from which priority is claimed. No new matter is added by the new claims.

Claims 22-35 are pending.

REQUEST FOR INTERFERENCE WITH PATENT UNDER 37 C.F.R. §1.607

Applicant respectfully requests that an interference be declared between the application and US 5,827,321 to Roubin, issued October 27, 1999. Claims 22-34 have been copied from the Roubin patent and correspond to claims 1-7, 9, 13-16 and 20 of Roubin. With the submission of this Preliminary Amendment, the claims have been copied within one year of issuance of the Roubin patent.

Proposed Count:

A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

Claims of Patent corresponding to proposed count:

Claim 1 of Roubin corresponds to the proposed count verbatim. Claims 2-7, 9, 13-16 and 20 dependent thereon correspond to the proposed count.

1. A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

Claims of application pending in application within one year of patent issuance:

22. A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

23. The stent of claim 22, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.

24. The stent of claim 23, wherein the connecting members are connected to the apices of the adjacent annular members.

25. The stent of claim 23, wherein the plurality of struts comprises left and right struts, with each pair of left and right struts connected to each other at an apex.

26. The stent of claim 23, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state.

27. The stent of claim 23, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.

28. The stent of claim 23, wherein at least one of the annular elements is closed such that the plurality of alternating struts and apices are connected to each other to form a closed annular element.

29. The stent of claim 22, wherein at least one of connecting member has a plurality of alternating segments.

30. The stent of claim 29, wherein the at least one connecting member has a plurality of alternating and angled straight segments.

31. The stent of claim 22, wherein each connecting member has a larger longitudinal dimension when each annular element is in the expanded state than in the compressed state to compensate for the smaller longitudinal dimension of the annular element in the expanded state.

32. The stent of claim 22, wherein each connecting member has a smaller longitudinal dimension when each annular element is in the compressed state than in the expanded state to compensate for the larger longitudinal dimension of the annular element in the compressed state.

33. The stent of claim 22, wherein the stent has a plurality of segments along its length, each segment assuming a different diameter when the annular elements are in their expanded state.

34. The stent of claim 22, wherein the annular elements and connecting members define an alternating longitudinal pattern of annular elements and connecting members.

Correspondence of Claim 23-34 to the Count:

Claims 23-34 are dependent claims from independent claim 22 listed above.

Application of Claims 22-34 to the Specification

22. A stent comprising:	Figs 11a and 11b
a plurality of annular elements,	annular elements labeled 110
each annular element having a compressed state and an expanded state,	see 110 in Figs. 11a and 11b
wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and	see 110 in Figs. 11a and 11b - element 110 inherently reduces in length in the expanded state

connecting members connecting adjacent annular elements;

see 112 in Figs. 11a and 11b

wherein the annular elements and connecting members are made of Nitinol,

specification page 7, lines 12-16,

with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

elongation of 112 shown in Fig. 11b

23. The stent of claim 22, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.

alternating struts 114
apices 116

24. The stent of claim 23, wherein the connecting members are connected to the apices of the adjacent annular members.

shown in both Figs. 11a and 11b

25. The stent of claim 23, wherein the plurality of struts comprises left and right struts, with each pair of left and right struts connected to each other at an apex.

left struts 114a
right struts 114b

26. The stent of claim 23, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state.	struts 114 orient at an oblique angle relative to longitudinal axis of stent as shown in Fig. 11b thereby resulting in reduced longitudinal dimension on expansion
27. The stent of claim 23, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.	see comments for claim 26
28. The stent of claim 23, wherein at least one of the annular elements is closed such that the plurality of alternating struts and apices are connected to each other to form a closed annular element.	all of annular elements 11 are closed
29. The stent of claim 22, wherein at least one of connecting member has a plurality of alternating segments.	see segments 112a-c
30. The stent of claim 29, wherein the at least one connecting member has a plurality of alternating and angled straight segments.	segments 112c are angled relative to the longitudinal axis of the stent
31. The stent of claim 22, wherein each connecting member has a larger longitudinal dimension when each annular element is in the expanded state than in the compressed	see element 112 in Fig. 11b

state to compensate for the smaller longitudinal dimension of the annular element in the expanded state.

32. The stent of claim 22, wherein each connecting member has a smaller longitudinal dimension when each annular element is in the compressed state than in the expanded state to compensate for the larger longitudinal dimension of the annular element in the compressed state.	see above comments for claim 31
33. The stent of claim 22, wherein the stent has a plurality of segments along its length, each segment assuming a different diameter when the annular elements are in their expanded state.	see Figs. 11a and 11b
34. The stent of claim 22, wherein the annular elements and connecting members define an alternating longitudinal pattern of annular elements and connecting members.	see Figs. 11a and 11b

Prima Facie Showing of Entitlement to Judgement

The instant application is a continuation of US Application 08/737,492 which is a National Stage Application based on PCT/US95/06228 filed May 18, 1995, claiming priority as a Continuation-in-Part of US Application 08/246,320 filed May 19, 1994. The disclosure which is relied upon in support of the instant claims is found in 08/246,320 filed May 19, 1994.

PCT/US95/06228 published as WO 95/31945 November 30, 1995. US 5,827,321 to Roubin was filed February 7, 1997. The instant application, therefore, predates Roubin in excess of two years. A copy of the Roubin patent accompanies this Preliminary Amendment. Moreover, the published PCT application WO 95/31945 anticipates Roubin under 35 U.S.C. 102(b).

Claim 35

Claim 35 recites an additional, patentably distinct limitation which renders the claim further patentable over claim 22 from which it depends. The subject matter associated with the additional limitations presented by claim 35 has been found to be allowable in US Application 08/246,320 from which priority is claimed. Prosecution of US Application 08/246,320 has been suspended because of a potential interference. It is noted, however, that the claims in that application do not include the limitations provided in claim 22 from which claim 35 depends.

It is also noted that the subject matter of this claim anticipates the Roubin claims discussed above.

CONCLUSION

In light of the above comments, allowance of claim 35 is respectfully requested. It is further requested, as to claims 22-34 that an interference be declared and that priority of invention be adjudged to the instant Applicant.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: October 26, 1999

By: _____

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DOCKET NO. S63.2-8606

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

INVENTOR(S):	Paul H. Burmeister, Charles L. Euteneuer, Brian J. Brown, Paul J. Fordenbacher, Anthony C. Vrba
TITLE:	IMPROVED TISSUE SUPPORTING DEVICES
ATTORNEYS:	Jonathan Grad VIDAS, ARRETT & STEINKRAUS Suite 2000 6109 Blue Circle Drive Minnetonka, MN 55343-9131 Phone: (612) 563-3000 Facsimile: (612) 563-3001

IMPROVED TISSUE SUPPORTING DEVICES

Background of the Invention

This invention relates to tissue supporting devices in general and most particularly to vascular stents for placement in blood vessels. A primary feature of the devices of this invention is that they are expandable within the body.

In the past, such devices have been provided for implantation within body passageways. These devices have been characterized by the ability to be enlarged radially, often having been introduced into the desired position in the body as by percutaneous techniques or surgical techniques.

These devices are either expanded mechanically, such as by expansion of a balloon positioned inside the device, or are capable of releasing stored energy to self-expand themselves within the body.

The materials which have been used to make up these devices have included ordinary metals, shape memory alloys, various plastics, both biodegradable and not, and the like.

This invention is concerned with the use of these materials in a new multiple component arrangement which allows for initial self-expansion and subsequent deformation to a final enlarged diameter in the body.

Balloon expandable stents do not always expand uniformly around their circumference. As a result, healing may not take place in a consistent manner. If the stent is coated or covered, non-uniform expansion may tear the covering or coating. Additionally, long stents of this type may require long balloons which can be difficult to handle, difficult to size, and may not offer ideal performance in tortuous passages in blood vessels and the like.

Thus, when addressing such issues, self-expandable stents have been thought to be generally more desirable. Unfortunately, one cannot control the degree of expansion and hence the degree of embedment in the vessel wall. It has been determined that a stent must be embedded to some degree to be clinically satisfactory.

The stents of the present invention provide the best features of both of these types of stents without their drawbacks.

Summary of the Invention

The tissue supporting devices of this invention are generally cylindrical or tubular in overall shape and of such a configuration as to allow radial expansion for enlargement. They are often referred to herein in the general sense as "stents". Furthermore, the devices are comprised of at least one component, element, constituent or portion which exhibits a tendency to self-expand the device to an expanded size and at least one other component, element, constituent or portion which is deformable so as to allow an external force, such as a balloon positioned within the body of the device, to further expand it to a final, larger desired expanded size. The terms "component", "element", "constituent" and "portion" are often referred to herein collectively as "portion".

Preferably, the devices of the invention are made of metal and most preferably of shape memory alloys.

In one embodiment, a first portion is a resilient spring-like metal for self-expansion and a second portion is a deformable metal for final sizing. In a more preferred shape memory embodiment, a first portion is a self-expanding austenitic one and a second is a martensitic one capable of deformation. In the case of shape memory embodiments the "portions" may be discrete or merely different phases of an alloy.

The most preferred embodiment of the invention is a stent, preferably of shape memory alloy. The most preferred shape memory alloy is Ni-Ti, although any of the other known shape memory alloys may be used as well. Such other alloys include: Au-Cd, Cu-Zn, In-Ti, Cu-Zn-Al, Ti-Nb, Au-Cu-Zn, Cu-Zn-Sn, Cu-Zn-Si, Cu-Al-Ni, Ag-Cd, Cu-Sn, Cu-Zn-Ga, Ni-Al, Fe-Pt, U-Nb, Ti-Pd-Ni, Fe-Mn-Si, and the like. These alloys may also be doped with small amounts of other elements for various property modifications as may be desired and as is known in the art.

The invention will be specifically described hereinbelow with reference to stents, a preferred embodiment of the invention although it is broadly applicable to tissue support devices in general.

<u>Brief Description of the Figures</u>

Figure 1 is a braided stent according to one embodiment of this invention.

Figure 2 is a graph showing the martensitic/austenitic temperature transformation curve and the superelastic area of a shape memory alloy.

Figures 3 is an end view of a layered stent having two discrete components according to one aspect of this invention.

Figures 4a and 4b are graphs showing the martensitic/austenitic temperature transformation curves of the layers in the stent of Figure 3.

Figure 5a and 5b are views of another embodiment of the invention comprised of alternating rings of shape memory alloy.

Figure 6 is a showing of a stent fragment of a braided version of a shape memory stent of this invention.

Figure 7 is a graph showing a temperature window for a shape memory alloy to be used in yet another stent version of this invention.

Figure 7a is a graph showing expansion of a stent with temperature.

Figure 7b is a graph of the same type, the stent having been cold-worked.

Figure 7c is a graph of the same type, the stent having had pseudoelastic prestraining.

Figure 7d is a graph of the same type, the stent having amnesia inducement.

Figures 8-11 show various expandable configurations (closed and open) illustrated in fragment which may be used in the stents of this invention. Figures 9a and 9b show a preferred embodiment of an articulated stent.

Figure 12 shows another version of an expandable stent of the invention.

Figure 13 shows yet another version of a stent which may be used with the invention.

Figure 14 is a schematic showing of a braided stent made up of a plurality of strands.

Figure 15 is a detail of a single strand from the stent of Figure 14 showing that the strand is made up of a plurality of wires of two different types.

Figure 16 is a cross-sectional view taken along line 16-16 of Figure 15 showing the two different types of wire.

Detailed Description of the Invention

Preferred embodiments of this invention are described below with particular reference to the accompanying drawing Figures.

Referring first to the embodiment shown in Figure 1, a stent 10 is shown comprised of braided or interwoven metal strands 12 and 14. Strands 12 are of a resilient spring-like metal such as spring steel, Elgiloy for example. Preferably, strands 12 are spirally extending in the same direction, spiraling to the right as seen in Figure 1. Strands 14 are of a deformable or annealed metal such as stainless steel and are preferably spiraled in the opposite direction as strands 12, as shown in Figure 1.

Given such a stent construction of two components *i.e.*, strands 12 and 14, it can be seen that stent 10 may be readily loaded on a catheter as by placing it over an uninflated balloon on a balloon catheter and compressing it tightly around the balloon and then placing a sheath over the stent to hold it in place during the transluminal placement procedure. Once in place, the sheath is removed, for example slid back, to expose the stent, allowing it to self-expand by force of the resilient strands 12 to substantially assume a self-expanded shape/size. Some self-expansion may be restrained if held back by strands 14. To finally adjust the size of the stent, the balloon may be expanded by inflation from within the stent to exert an outward radial force on the stent and further enlarge it by stretching and deforming the deformable metal of strands 14. This may be aided by building into strands 14, a series of readily deformable structures or means such as bends or kinks 16 as shown in Figure 1. It can be seen that a permanent adjustable size beyond the self-expanded size may be obtained with this embodiment. It is to be noted that many configurations other than braided may be readily devised to take advantage of this two component concept, including various of the subsequent configurations described hereinbelow. Also, it should be noted that, although not preferred, the stent may be initially deployed without a balloon; the balloon following on a separate catheter.

Referring now to subsequent features, other preferred embodiments of the invention will be described which make use of shape memory alloys and some of their unique properties, primarily their special types of deformation i.e., shape memory deformation in martensite and/or superelastic deformation in austenite.

The term "superelasticity" is used to describe the property of certain shape memory alloys to return to their original shape upon unloading after a substantially deformation while in their austenitic state. Superelastic alloys can be strained while in their austenitic state more than ordinary spring materials without being plastically deformed. This unusually large elasticity in the austenitic state is also called "pseudoelasticity", because the mechanism is nonconventional in nature, or is also sometimes referred to as "transformational superelasticity" because it is caused by a stress induced phase transformation. Alloys that show superelasticity also undergo a thermoelastic martensitic transformation which is also the prerequisite for the shape memory effect. Superelasticity and shape memory effects are therefore closely related. Superelasticity can even be considered part of the shape memory effect.

The shape memory and superelasticity effects are particularly pronounced in Ni-Ti alloys. This application will therefore focus on these alloys as the preferred shape memory alloys. The shape memory effect in Ni-Ti alloys has been described many times and is well known.

In near-equiatomic Ni-Ti alloys, martensite forms on cooling from the body centered cubic high temperature phase, termed austenite, by a shear type of process. This martensitic phase is heavily twinned. In the absence of any externally applied force transformation takes place with almost no external macroscopic shape change. The martensite can be easily deformed by a "flipping over" type of shear until a single orientation is achieved. This process is also called "detwinning".

If a deformed martensite is now heated, it reverts to austenite. The crystallographic restrictions are such that it transforms back to the initial orientation thereby restoring the original shape. Thus, if a straight piece of wire in the austenitic condition is cooled to form martensite it remains straight. If it is now deformed by bending, the twinned martensite is converted to deformed martensite. On heating, the

transformation back to austenite occurs and the bent wire becomes straight again. This process illustrates the shape memory deformation referred to above.

The transformation from austenite to martensite and the reverse transformation from martensite to austenite do not take place at the same temperature. A plot of the volume fraction of austenite as a function of temperature provides a curve of the type shown schematically in Fig. 2. The complete transformation cycle is characterized by the following temperatures: austenite start temperature (A_s), austenite finish temperature (A_f), both of which are involved in the first part (1) of an increasing temperature cycle and martensite start temperature (M_s) and martensite finish temperature (M_f), both of which are involved in the second part (2) of a decreasing temperature cycle.

Figure 2 represents the transformation cycle without applied stress. However, if a stress is applied in the temperature range between A_s and M_d, martensite can be stress-induced. Stress induced martensite is deformed by detwinning as described above. Less energy is needed to stress induce and deform martensite than to deform the austenite by conventional mechanisms. Up to about 8% strain can be accommodated by this process (single crystals of specific alloys can show as much as about 25% pseudoelastic strain in certain directions). As austenite is the thermodynamically stable phase at temperatures between A_s and M_d under no-load conditions, the material springs back into its original shape when the stress is no longer applied.

It becomes increasingly difficult to stress-induce martensite at increasing temperatures above A_f. Eventually, it is easier to deform the material by conventional mechanisms (movement of the dislocation, slip) than by inducing and deforming martensite. The temperature at which martensite can no longer be stress-induced is called M_d. Above M_d, Ni-Ti alloys are deformed like ordinary materials by slipping.

Additional information regarding shape memory alloys is found in the following references, all of which are incorporated fully herein by reference:

"Super Elastic Nickel-Titanium Wires" by Dieter Stöckel and Weikang Yu of Raychem Corporation, Menlo Park, California, copy received November 1992;

Metals Handbook, Tenth Edition, Vol. 2, *Properties and Selection: Nonferrous Alloys and Special-Purpose Materials*, *"Shape Memory Alloys"* by Hodgson, Wu and Biermann, pp. 897 - 902; and,

In Press, *Titanium Handbook*, ASM (1994), Section entitled *"Structure and Properties of Ti-Ni Alloys* by T.W. Duerig and A.R. Pelton.

Since the most preferred shape memory alloy is Ni-Ti, the martensitic state of this alloy may be used to advantage in the two component concept of this invention.

For example, with reference to Figure 3, a layered construction may be provided in a stent 30 (shown in end view) which is generally a hollow cylindrical or tubular body in shape but which may be formed in a wide variety of specific configurations or patterns to foster radial expansion of the body as exemplified in Figures 1, 5, 6 and in subsequent Figures 8-11.

Stent 30 is comprised of at least two layers 32 and 34, one of which 32 is a Ni-Ti alloy (50.8 atomic wt. % Ni, balance Ti, transition temperature of A_f=0° C) and normally in the austenitic state, the other of which 34 is a Ni-Ti (49.4 atomic wt. % Ni, balance Ti, transition temperature A_f = 60° C) and normally in the martensitic state. Preferably, the inner layer is 32 and the outer layer is 34. However, this may be reversed and also a plurality of layers, alternating or otherwise, may be utilized in this particular embodiment.

Stent 30 is made to a fabricated size and shape (parent shape) which provides austenitic layer 32 its parent shape and size *i.e.*, its superelastic high temperature shape and size. Obviously, in its as fabricated condition, the Ni-Ti alloy of austenitic layer 32 is selected so as to have a transition temperature range between its austenitic and martensitic states which is lower than body temperature as to ensure that in the body and at body temperatures the austenitic state will always prevail.

On the other hand, martensitic layer 34 is of a Ni-Ti alloy having a transition temperature range significantly greater than body temperature so as to ensure that under body conditions the martensitic state will always prevail and the alloy will never transform to austenite in stent use. This is shown in the graphs of Figure 4a and 4b which demonstrate the relative transition temperatures of layers 32

and 34, respectively for purposes of this invention. It can be seen from these graphs that the normal condition of layer 32 (Figure 4a) at body temperatures and higher is the austenitic state while the normal condition of layer 34 (Figure 4b) at body temperatures is martensitic.

To manufacture the layered construction, one may make the austenitic portion with any standard metallurgical technique and vapor deposit the martensitic portion on its surface. Other manufacturing techniques such as diffusion bonding, welding, ion beam deposition, and various others will be apparent to those familiar with this art.

Such a stent may be compressed or constrained (deformed to a small diameter) onto a balloon catheter as described for the previous embodiment and captured within a sheath. During the constrainment, austenitic layer 32 may stress induce to a martensitic state. In the alternative, the stent may be cooled below the transition temperature of layer 32 to facilitate its deformation and constrainment. Martensitic layer 34 merely undergoes deformation. Thus the stent may be "loaded" onto a balloon catheter. However, with temperature changes occurring up to body temperature, layer 32 will remain martensite until the constraint is removed. When released in place in the body, stent 30 will expand to a percentage of its self-expanded size and shape due to the transformation of layer 32 from martensite to austenite at which point the balloon may be used to radially expand the stent to a greater permanent diameter by deforming martensitic layer 34. On the other hand, initial deployment can take place without a balloon which may be separately inserted after deployment.

The two component concept of the invention in the layered embodiment of Figure 3 requires both the martensitic and austenitic phase characteristics of shape memory alloy(s) in the two discrete components 32 and 34.

Preferably, the stent is fabricated in such a way that the austenitic layer 32 tends to self-expand stent 30 to a predetermined fabricated diameter (parent shape). The martensitic layer 34 tends to hold back this self-expansion, preventing full expansion. For example, the stent may only be able to self-expand to 75% of its full possible diameter (as determined by the austenitic layer). Therefore, expansion beyond 75% is accomplished by an applied external force, as by the balloon inside the

stent. It is suggested that the stent not be expanded beyond its normal fabricated diameter for the austenitic layer 32 will have the tendency of making the stent diameter smaller as it tries to recover its fabricated diameter (parent shape). If the stent is subjected to a temperature above body temperature and above the transition temperature of the martensitic layer (which is clinically unlikely), the stent will self-expand to the fabricated diameter only. Depending on design size there are thus provided permanent stents capable of fulfilling any needed range of sizes with an adjustable sizing capability.

As is known in the art, the desired properties of the shape memory alloys required for use in this invention may be obtained by alloy composition and working and heat treatment of the alloys, in various combinations or singly.

Manufacturing techniques influence the phase characteristics of the material. Alloy composition, work history, and heat treatment all influence the final characteristics. At a specific operating temperature, say body temperature, the austenite phase material will have a transition temperature below body temperature (i.e., $A_f=0°C$). The material is capable of taking high strains and recovering after the load is released. The martensite phase material will have a higher transition temperature than body temperature (i.e., $A_f=60°C$), and is characteristically soft and pliable and retains the deformed shape after load removal. This martensite deformation is caused by detwinning, not the typical plastic deformation, or yielding, of crystal slip.

With reference to Figures 5 and 6, other stent constructions are shown which are similar to the layered version of Figure 3 in so far as utilization of the two component concept of this invention is concerned.

Figure 5a and 5b shows a stent 50 made up of alternating expandable rings 52 and 54 of austenitic and martensitic alloys, respectively, analogous to layers 32 and 34 of the Figure 3 embodiment. Rings 52 and 54 for example are interconnected by strut members 56 which may be of any material capable of rigidly holding the rings together. Other interconnector means may be used. As can be seen in Figure 5b, the placement of strut members 56 does not require them to take part in the radial expansion of the stent and they can therefore be of a relatively ordinary material such as stainless steel.

Referring now to Figure 6, a braided or interwoven construction is shown similar in construction to that of the embodiment of Figure 1. In this embodiment, strands 62 extending to the right in Figure 6 are an alloy in the austenitic state whereas strands 64 extending to the left in Figure 6 are an alloy in the martensitic state.

Referring now to the graph of Figure 7, it is demonstrated that the two component concept of the invention may be embodied in two phases, i.e., components of a single shape memory alloy and need not be in the form of two discrete components such as layers, members, wires, etc. In the graph of Figure 7, it can be seen that an alloy composition can be selected such that it has a phase transition temperature window that bounds the proposed operating temperatures of the stent, such as the normal body temperature range. Within this transitional window or zone, the material undergoes the phase transition and is effectively compositionally comprised of a ratio of austenitic to martensitic phase depending on the temperature of the stent. This ratio should be selected so as to provide sufficient radial force from the austenite phase while still allowing for further expansion of the martensite phase with a mechanical expansion means such as a balloon. Selecting body temperature as the operating temperature, a Ni-Ti alloy of about 50/50 atomic wt. % composition (range about 49/51%) will provide an acceptable "window" for this embodiment, the two components are the austenite and martensite phases of the nitinol.

The method of making a stent may be described as follows. Age the shape memory material (Ni Ti) until body temperature falls somewhere within the transformation window. Therefore the stent will not fully recover to its high temperature shape at body temperature. An example of this technique is described below.

A stent of tubular 50.8% Ni balance Ti was prepared having a 1.5 mm diameter. It was substantially all austenite at room temperature, the A_f being about 15-20°C and therefore being superelastic at room temperature. The stent was cooled to below room temperature to form substantially all martensite and mechanically expanded to 4.7 mm in diameter. It was maintained at the 4.7 mm in diameter and heat treated at 500°C for 30 minutes and water quenched. Finally, it was again cooled to below room temperature to form substantially all martensite and compressed

to a diameter of 1.5 mm. After deployment and at body temperature the stent has a diameter of 3.5 mm. At about 70% of full expansion, i.e., about 40°C it had a diameter of 4.5 mm and at 42°C it had a fully expanded diameter of 4.7 mm.

This method works fairly well, but due to the slope of the temperature versus diameter plot being extremely vertical at body temperature, a small change in body temperature, or manufacturing control, can have a large impact on the actual self expansion diameter. As can be seen from Figure 7, the slope of the line between A_f and A_s is rather steep with small changes in temperature leading to large changes in percent austenite and consequently large changes in diameter of a stent made of such an alloy. Figure 7a shows a temperature versus diameter plot. Three methods of modifying the slope of the line on the temperature versus diameter graph are cold work, pseudoelastic prestraining, and amnesia inducement, illustrated in Figures 7b, 7c and 7d, respectively.

COLD WORK

Residual cold work in nitinol draws out or masks the point of A_f on the diameter versus the temperature curve. This is seen by the sluggish increase in diameter as temperature increases in the last 20-30% of recover. By utilizing the effects of cold work, the effects of temperature change on diameter can be reduced in the last 20 to 30% of stent expansion. Shown in Figure 7b is an example of a temperature versus diameter plot for a cold worked part. Figure 7a above shows an example of a part without cold work.

PSEUDOELASTIC PRESTRAINING

Utilizing the effects of pseudoelastic prestraining (S. Eucken and T.W. Duerig, *ACTA Metal*, Vol. 37, No. 8, pp 2245-2252, 1989) one can create two distinct plateaus in the stress-strain behavior. This difference in stress strain behaviors can be directly linked to two distinct A_f temperatures for the two plateaus. By placing the transition between the two plateaus at the transition from self expanding to balloon expanding, i.e., 70%, one can control the characteristics of the stent at body temperature. The goal would be to place the A_f temperature for the first plateau (from maximum compression to 70% expansion) below body temperature such that the stent has self expanding characteristics. The A_f temperature for the second plateau would be above body temperature such that there is no additional self

expansion in this region (70 to 100% expansion) a mechanical device, like a balloon, can then be used to custom size the stent between 70% and 100% of the high temperature shape. Results of such a technique is shown in Figure 7c.

AMNESIA INDUCEMENT

One of the characteristics of nitinol is cycle amnesia. This was also discussed about in the article referred to immediately above. As nitinol is cycled from its heat set shape as shown in Figure 7d, there is an increase in the amount of amnesia to recover to the heat set shape with each cycle. As long as this amnesia is not caused by permanent plastic deformation, the amnesia can be removed by heating the part above M_d. This shows there is martensite left in the part after cycling which is preventing full recovery in the austenite phase (just above A_f). This presence of non recoverable martensite (below M_d) is what may be used for the balloon expansion region of the stent.

Figures 8-11 represent examples of various expandable configurations (a = closed, b = expanded) which may be incorporated into the devices of this invention. The version shown in Figures 10a and 10b may be modified as shown in Figures 10c and 10d (closed and open, respectively) by omitting portions (indicated at 100 in Figures 10c and 10d) as to render the stent flexible for articulation. This may be done to other of the structures as well to improve flexibility.

Yet another version of a device incorporating the two component concept of the invention is shown in Figure 12. In this embodiment, a fragment of a stent 110 is shown. The stent includes a self-expanding component 112 and a deformable, external force expandable component 114. Self expanding component 112 may be resilient spring-like metal such a stainless steel or it may preferably be a shape memory alloy in the austenitic state. Component 114 may be any deformable metal or the like such as annealed stainless steel or preferably a shape memory alloy in the martensitic state. The two components may simply be mechanically, welded or bonded together. Functions and operations are as described hereinabove.

Referring to Figure 13 a version analogous to the embodiment of Figure 12 is shown in which the two component concept is again embodied as different zones or portions of a single metal material.

As shown in Figure 13, a stent 120 (fragment showing) is of a self-expanding component 122 and a deformable component 124, both of which may be a single metal as spring steel or austenitic Ni-Ti which has been appropriately treated with respect to component 124 as by localized heat treatment or the like to alter the characteristics of the material of the 122 component so as to render it deformable or martensitic, depending on whether it is merely resilient or is austenitic. Again, function and operation are the same as with other embodiments.

Referring now to Figures 14-16, a multi-strand braided stent is shown in Figure 15. Each strand 150 in the stent is a micro-cable. That is, each strand is made up of a plurality of wires 152 and 154 as is seen in Figures 15 and 16. Each of the wires 152 and 154 consists of two different nitinol alloys as seen best in Figure 16, or one nitinol and one ordinary metal such as stainless steel, platinum or tantalum. The latter two would provide enhanced radiopacity. One nitinol alloy wire 154 has an austenitic finish (A_f) temperature less than body temperature. The other wire 152 could be nitinol having an A_s (austenitic start) greater than body temperature. Also, it could be an ordinary metal. Additionally, one or more of the strands may be of a biodegradable material such as a plastic or may be of a material including an absorbable drug.

Since the two alloys are stranded into micro-cable one does not have to engage in selective, discrete heat treating methods to produce both shape memory and martensitic effects.

Radiopaque portions or coatings may be included on any parts of these stents as is known in the prior art.

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described

herein which equivalents are also intended to be encompassed by the claims attached hereto.

WHAT IS CLAIMED

1. As a tissue supporting device a constrainable, self-expanding member of generally tubular shape comprised of first and second portions; first portion being of a resilient material; the second portion being of a deformable and substantially less resilient material than the first portion; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the device being self-expanding when unconstrained to an initially deployed diameter due to the resiliency of the first portion; the portions being so associated with respect to each other and the member such that the device may be further deformed due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

2. The device of claim 1 wherein the first and second portions are of metal.

3. The device of claim 2 wherein the first portion is a spring metal and the second portion is an annealed metal.

4. The device of claim 1 wherein the first and second portions are in the form of layers.

5. The device of claim 1 wherein the first and second portions are discrete portions in the circumference of the device body.

6. The device of claim 1 wherein the first and second portions are of shape memory alloy, austenite and martensite, respectively.

7. The device of claim 1 wherein the first and second portions are strands.

8. The device of claim 1 wherein the first and second portions are of a shape memory alloy.

9. A permanent self-expanding stent having a generally tubular body of a predetermined fabricated diameter comprised, at about normal body temperatures, of a shape-memory, superelastic, austenitic alloy portion and a shape memory, martensitic alloy portion, the superelastic austenitic alloy portion having a transition temperature from martensitic to austenitic less than body temperature while the martensitic alloy portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensitic alloy portion and superelastic austenitic alloy

portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two alloy portions act in combination to allow, upon transformation of the austenitic alloy portion to martensitic at a temperature below the transition temperature, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite alloy portion from martensite back to austenite to self-expand the stent back to about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenitic superelastic portion, the shape memory of the superelastic austenitic portion tending to form the stent to a larger diameter due to its shape memory but being restrained therefrom by the martensitic alloy portion whereby the austenitic alloy portion can be deformed by external force without plastic deformation along with the martensitic portion to an enlarged stent diameter beyond that of the self-expanded diameter.

10. The stent of claim 9 wherein the first and second portions are in the form of layers in overlying relationship.

11. The stent of claim 9 wherein the first and second portions are different phases in an alloy.

12. The stent of claim 9 wherein the first and second portions are in the form of strands.

13. The stent of claim 9 wherein the first and second portions are in the form of longitudinally arranged interconnected alternating rings.

14. The stent of claim 9 comprised of a plurality of cable-like strands and wherein each strand is comprised of a plurality of wires some of which are of the first portion and some of which are of the second portion.

15. A permanent self-expanding stent having a generally tubular body of a predetermined fabricated diameter-parent shape, comprised, at about normal body temperatures, of a shape-memory, superelastic, austenite phase portion and a shape memory, martensite phase portion, the superelastic austenite phase portion having a transition temperature from martensitic to austenitic less than body temperature while the martensite phase portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensite phase portion and superelastic austenite phase portion being constructed, arranged and associated with

respect to each other in comprising the stent such that the two portions act in combination to allow, upon transformation of the austenite phase portion to martensite, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite phase portion from martensite back to austenite to self-expand the stent back toward the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite superelastic portion, the shape memory of the superelastic austenitic portion tending to form the stent to the fabricated diameter parent shape due to its shape memory but being restrained therefrom by the martensite portion whereby the austenite portion recovery back toward the fabricated diameter can be assisted by external force along with the deforming of the martensitic portion without slip deformation to an enlarged stent diameter beyond that of the restrained self-expanded diameter.

16. As a tissue supporting device, a constrainable, self-expanding member of generally tubular shape comprised of first and second portions of nickel-titanium shape-memory alloy; the first portion alloy having martensitic and austenitic superelastic shape memory metallurgical states and a transition temperature therebetween, the transition temperature being at less than body temperature; the second portion alloy having martensitic and austenitic metallurgical states and a transition temperature therebetween, the transition temperature being substantially higher than body temperature, said first portion alloy being transformable from austenitic to the martensitic state when cooled below its transition temperature so as to render both alloy portions in the martensitic state whereby the member is constrainable to a deployable diameter in preparation for insertion into a patient, during which the first portion alloy may transform to the austenitic state while constrained, the second portion alloy being and remaining in the martensitic state; the stent being self-expanding at body temperature when unconstrained to an initially deployed diameter due to the first portion alloy being in the austenitic state and the second portion alloy being in the martensitic state, the alloy portions being so associated with respect to each other and the member such that the second portion alloy restrains the first portion so that the member assumed the initially deployed diameter, because of the restriction of the austenitic superelastic alloy from the full

exercise of its shape memory and whereby the alloy portions may be further deformed by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

17. A self-expanding stent comprised of at least two components arranged for coaction, the first component being substantially austenite and the second being substantially martensite.

18. The stent of claim 16 wherein the first component is a nitinol alloy.

19. The stent of claim 16 wherein the first component is superelastic and the second component is any deformable material.

20. As a tissue supporting device, a constrainable, self-expanding member of generally tubular shape comprised of nickel-titanium shape memory alloy containing components of both martensite and austenite phases, the transition temperature being at about body temperature, said alloy being transformable to the fully martensitic state when cooled below its transition temperature so as to render it to the martensitic state whereby the member is more easily constrainable to a deployable diameter in preparation for insertion into a patient; the stent being self-expanding at body temperature when unconstrained to an initially deployed diameter due to a portion of the alloy being in the austenitic state and a portion of the alloy being in the martensitic state, the alloy portions being so associated with respect to each other and the member such that the member assumes the initially deployed diameter, upon self-expansion and the alloy portions may be further deformed by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

21. A permanent self expanding stent having a generally tubular body of a predetermined fabricated diameter-parent shape, comprised, at about normal body temperatures, of a shape-memory, superelastic, austenite phase portion and a shape memory martensite phase portion, the superelastic austenite phase portion having a transition temperature from martensitic to austenitic less than body temperature while martensite phase portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensite phase portion and superelastic austenite phase portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two portions act

independently to allow, upon transformation of the austenite phase portion to martensite, constraint of both of the original phase portions of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite phase portion from martensite back to austenite to self-expand the stent back to the austenite phase portion predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite superelastic portion, the shape memory of the superelastic austenitic portion tending to form the austenitic portions of the stent to the fabricated diameter parent shape due to its shape memory, with the martensitic portions remaining in the deployment shape, additional recovery back toward the stent fabricated diameter parent shape can be assisted by an external force deforming the martensitic portion without slip deformation to an enlarged stent diameter beyond that of the self-expanded austenitic portion diameter, but not greater than the stent fabricated diameter parent shape.

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ABSTRACT OF THE DISCLOSURE

IMPROVED TISSUE SUPPORTING DEVICES

A new multiple component stent arrangement which allows for initial self-expansion and subsequent deformation to a final enlarged size.

Fig. 1

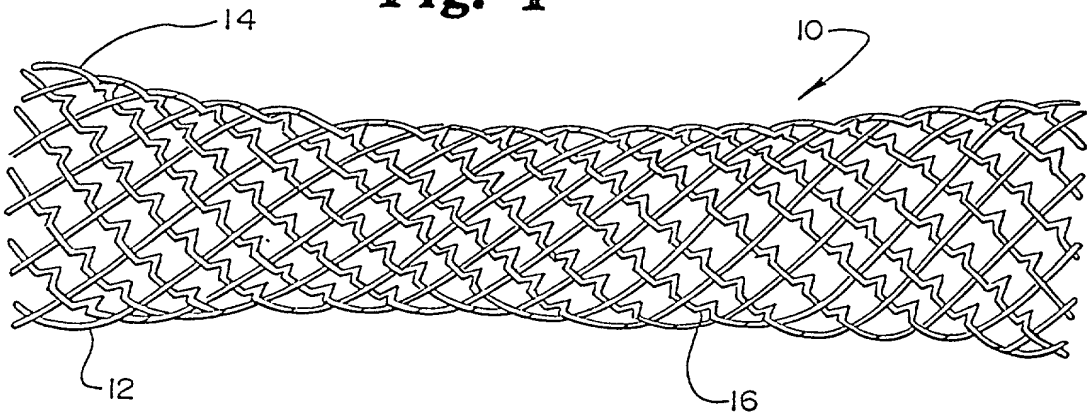


Fig. 2

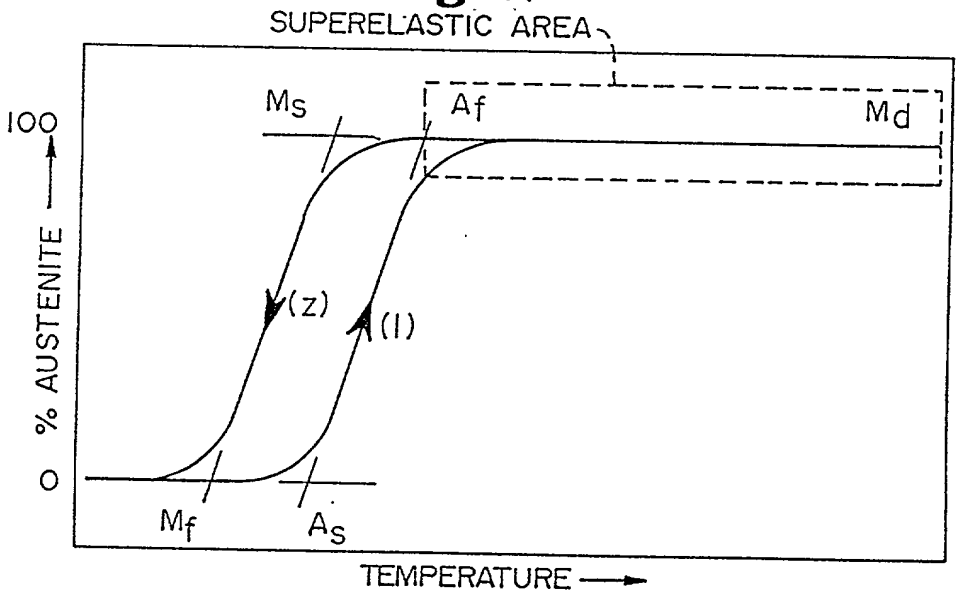


Fig. 3

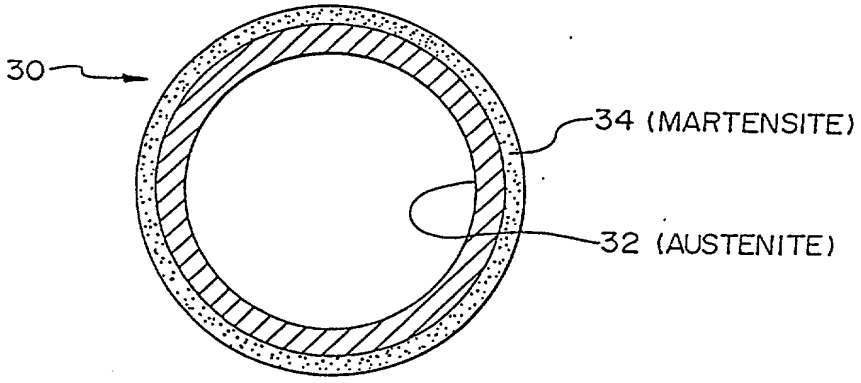


Fig. 4a (LAYER 32)

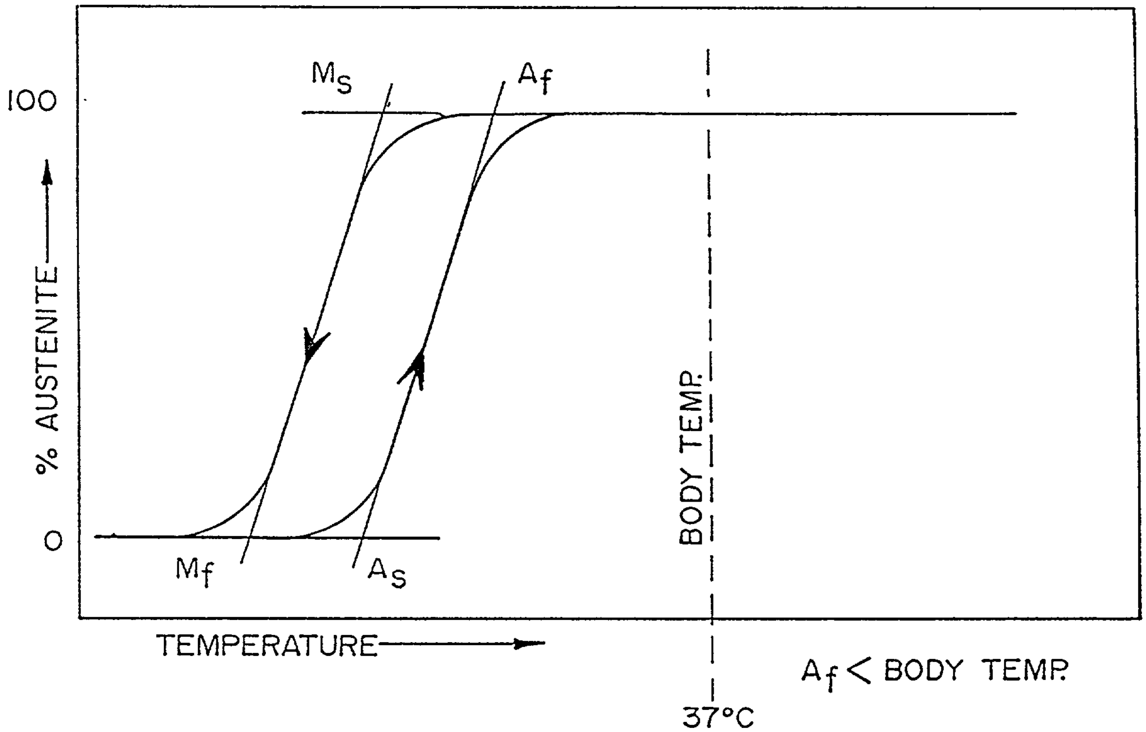


Fig. 4b (LAYER 34)

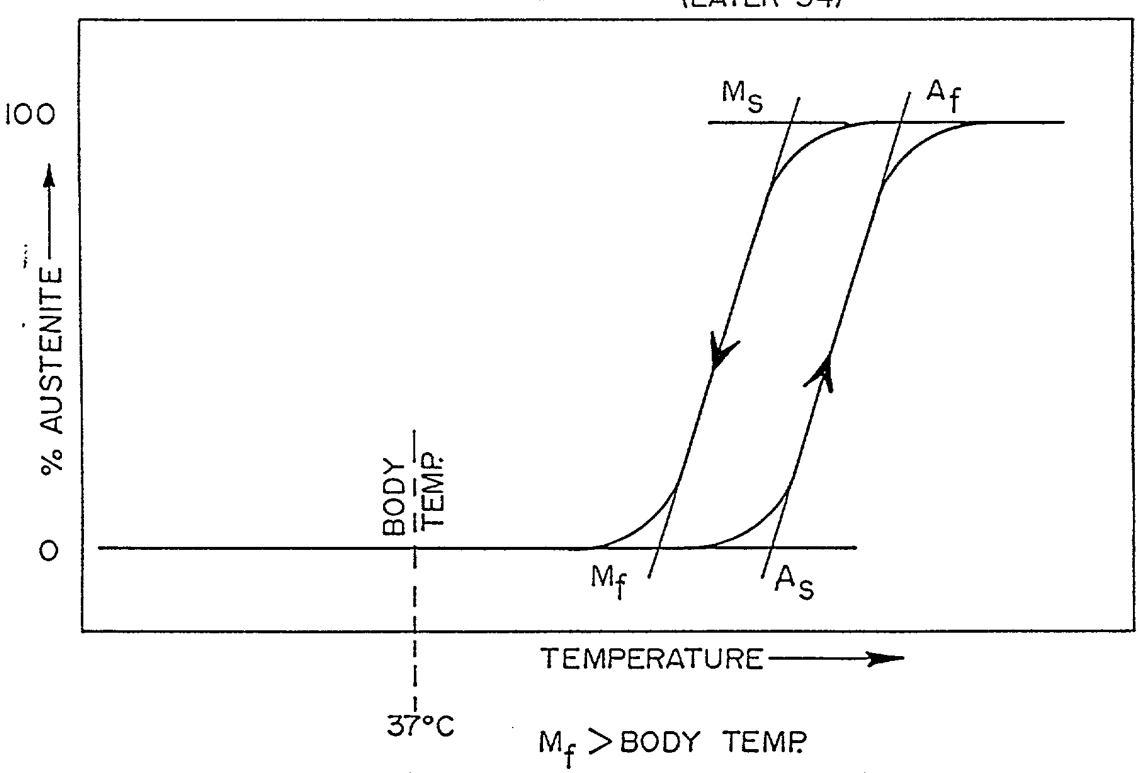


Fig. 5a

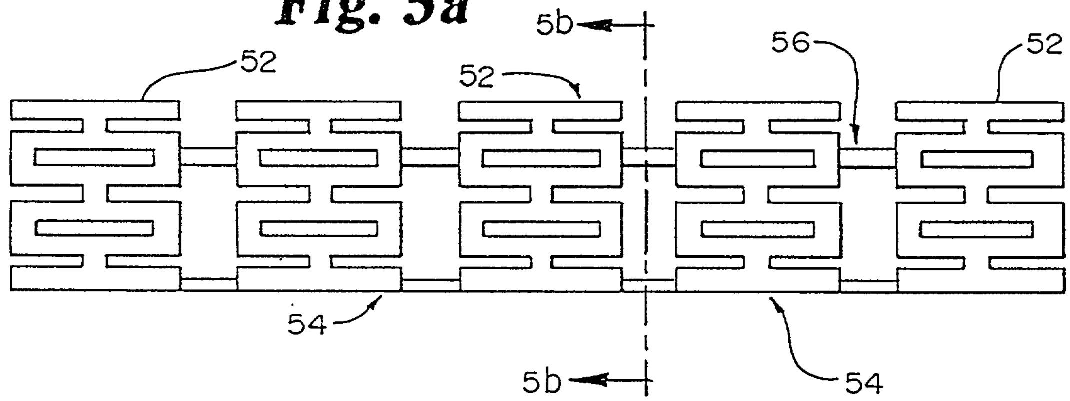


Fig. 5b

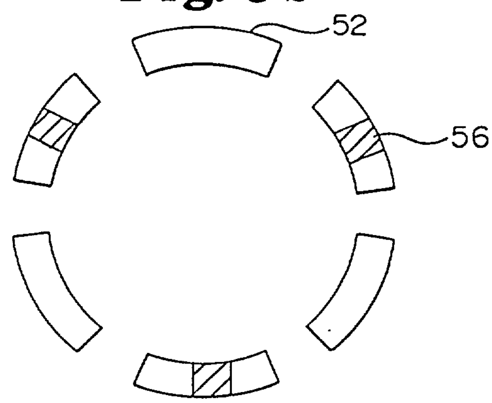


Fig. 6

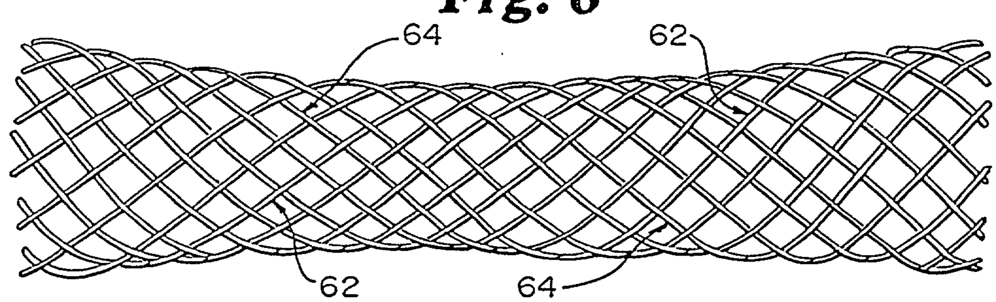


Fig. 7

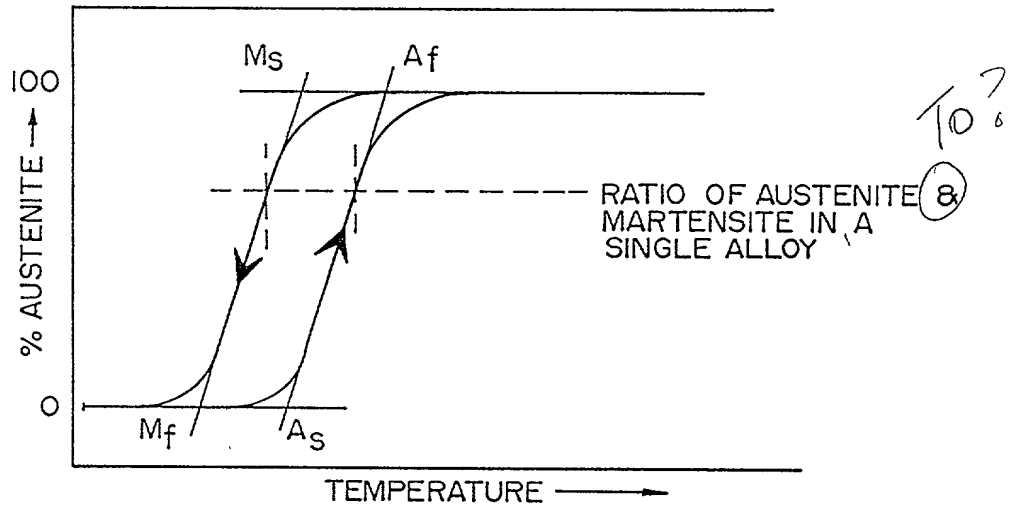


Fig. 8a

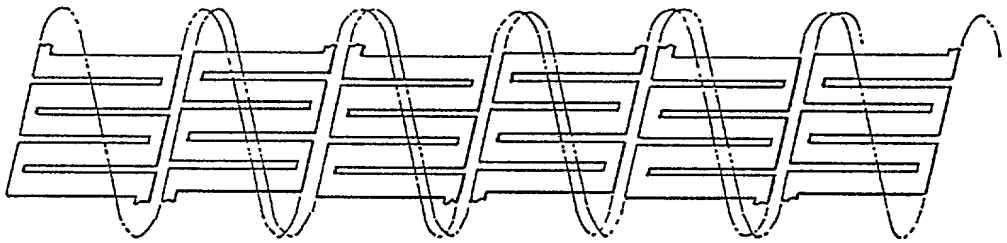


Fig. 8b

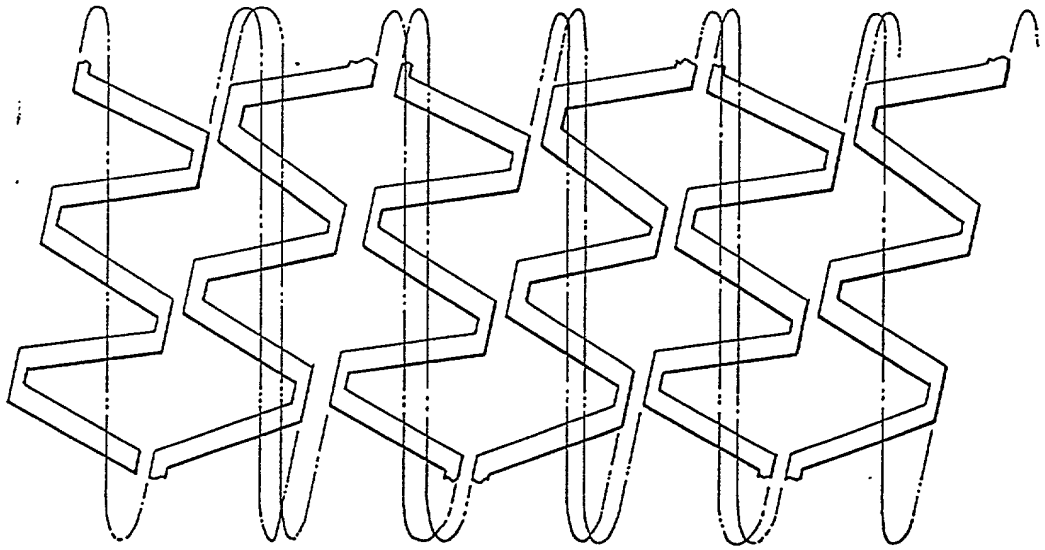


Fig. 7a

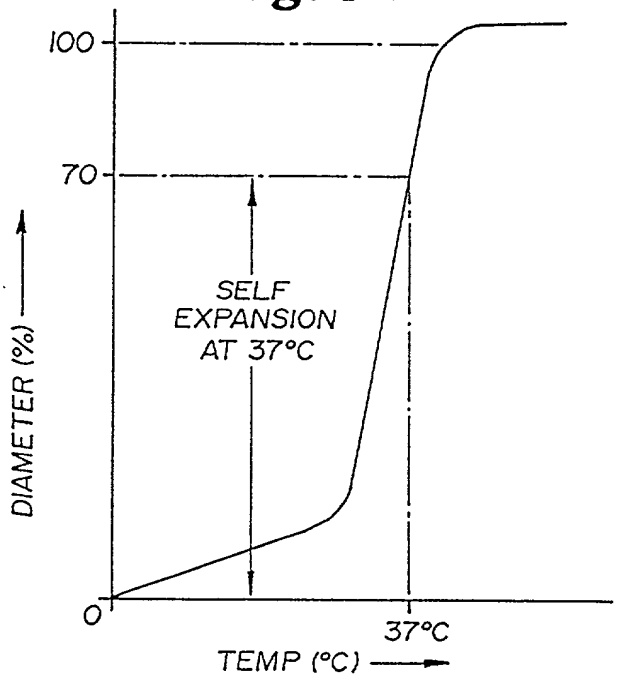

100
70
0
SELF
EXPANSION
AT 37°C
DIAMETER (%)
37°C
TEMP (°C)

Fig. 7b

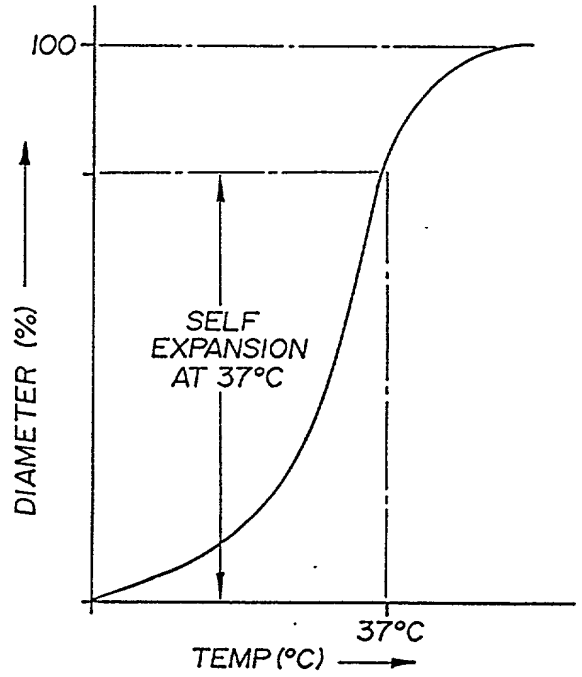

100
SELF
EXPANSION
AT 37°C
DIAMETER (%)
37°C
TEMP (°C)

Fig. 7c

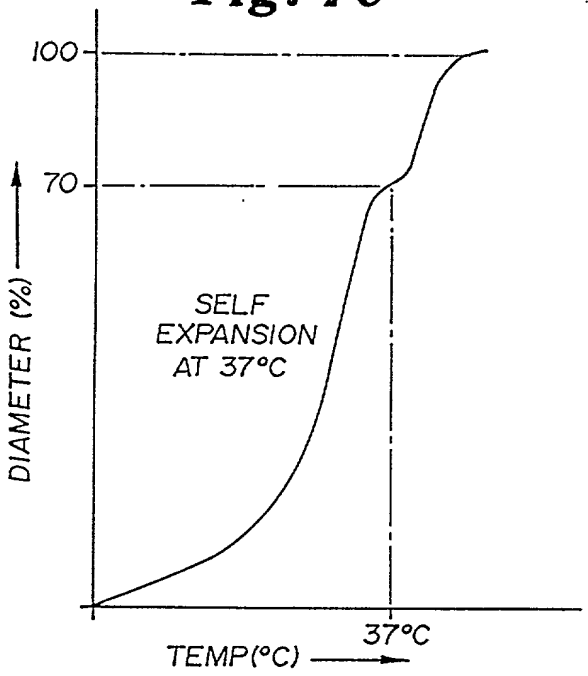
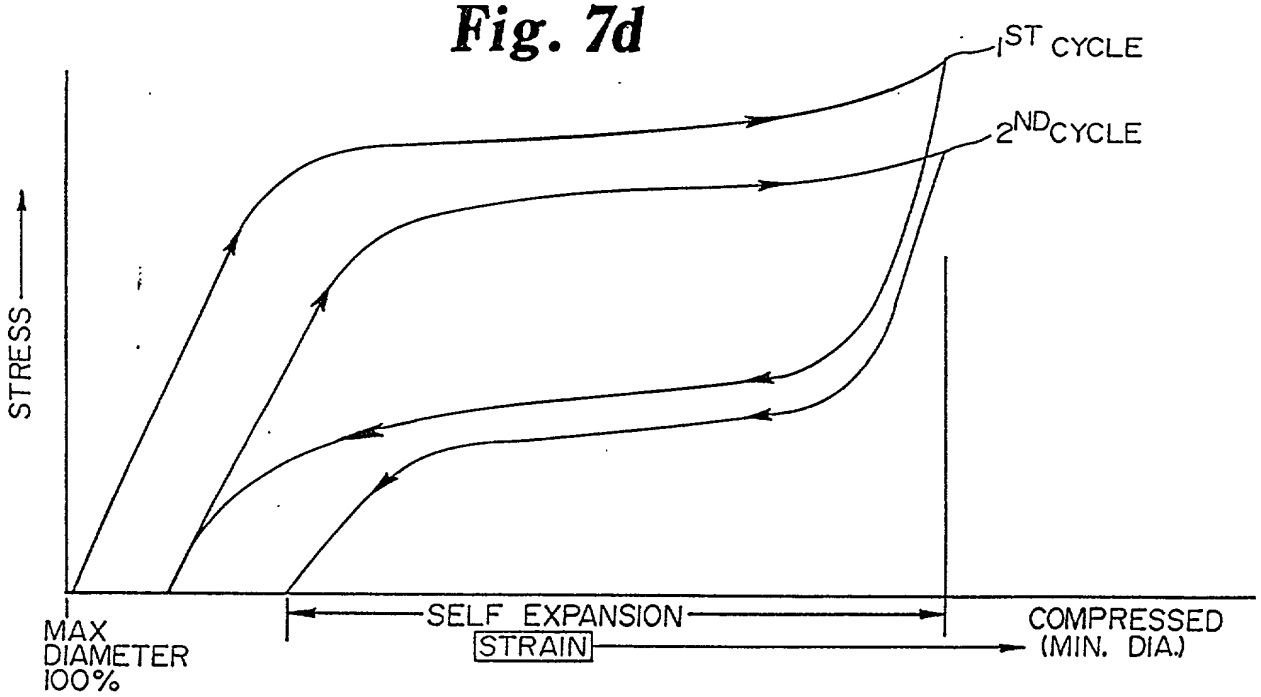


Fig. 7d



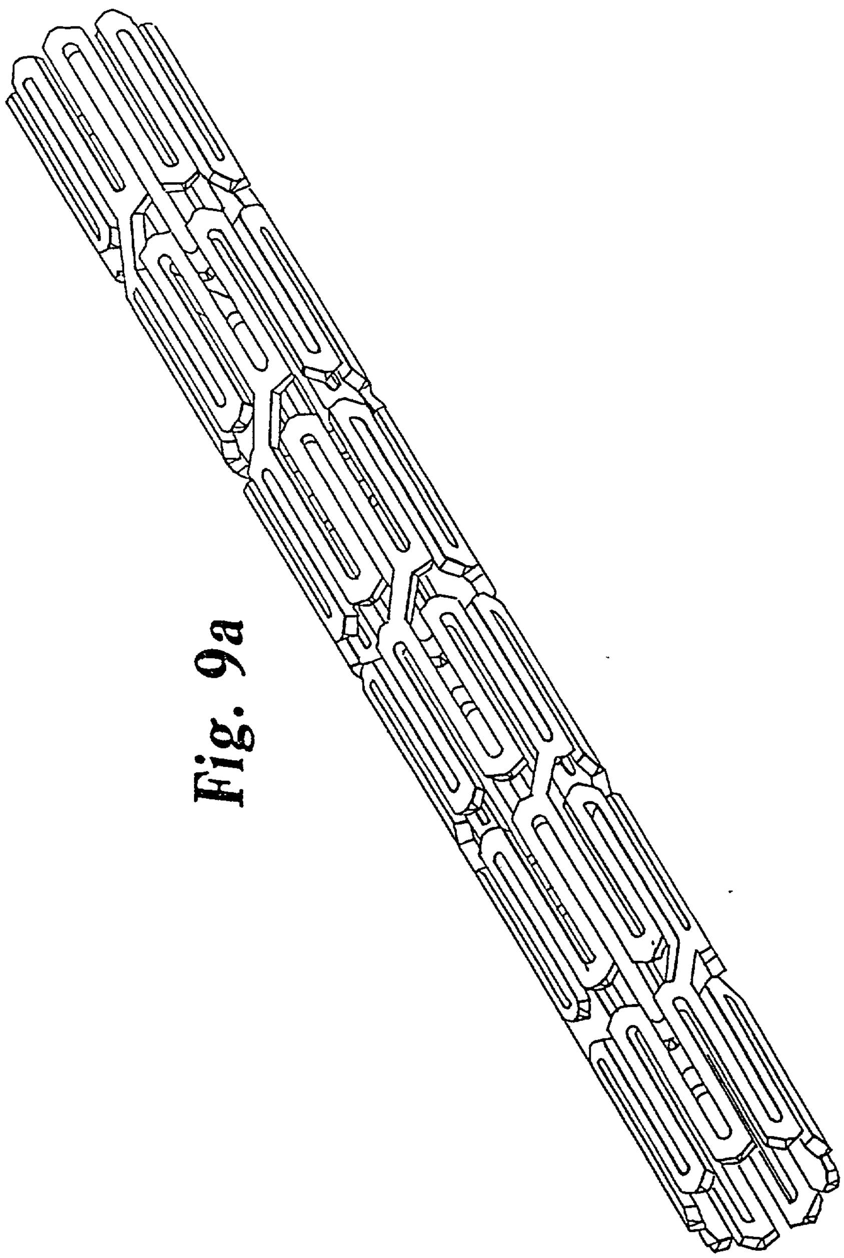


Fig. 9a

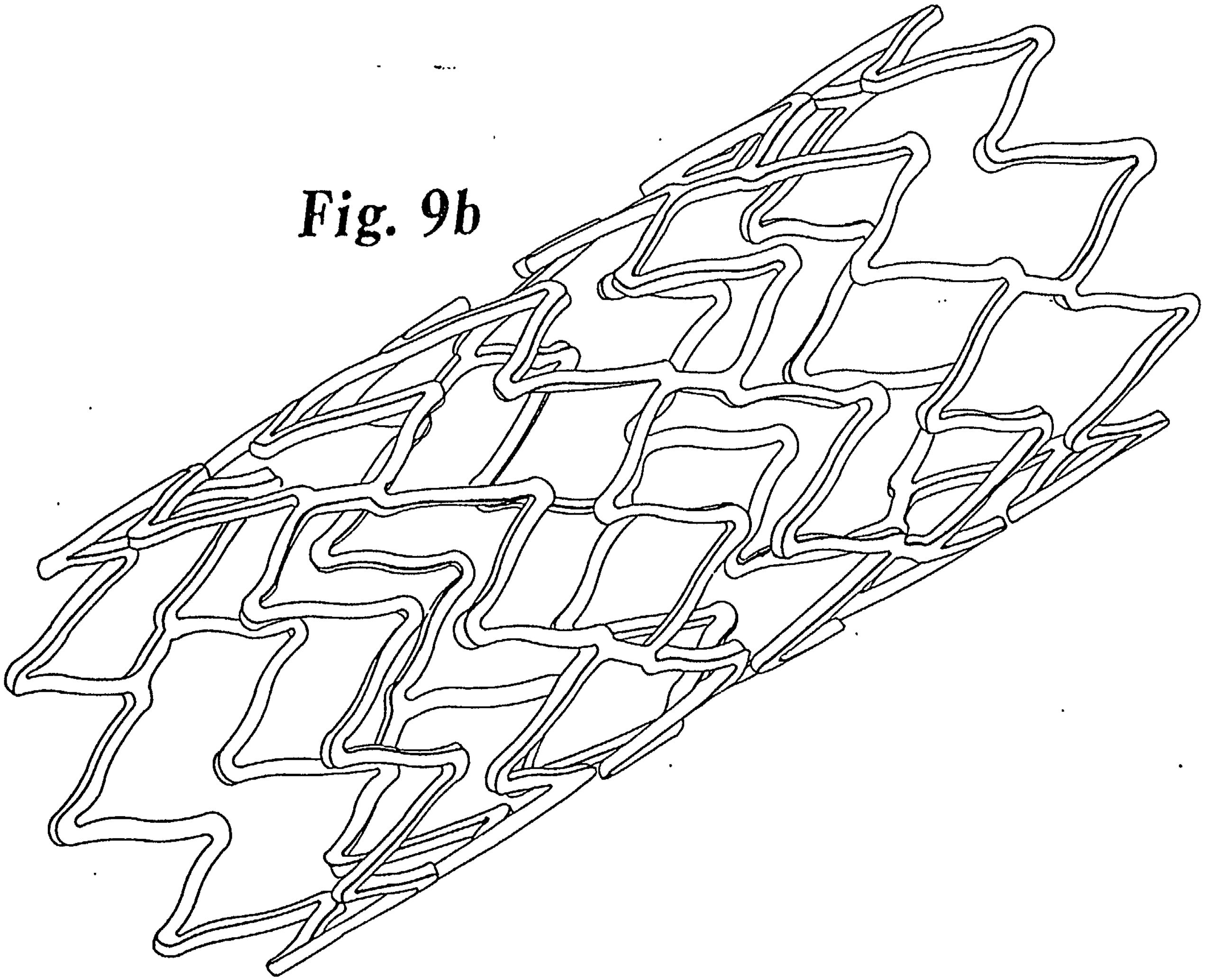


Fig. 9b

Fig. 10a

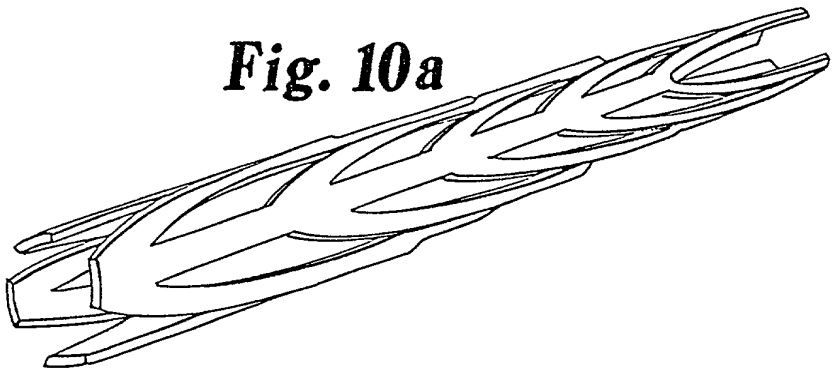


Fig. 10b

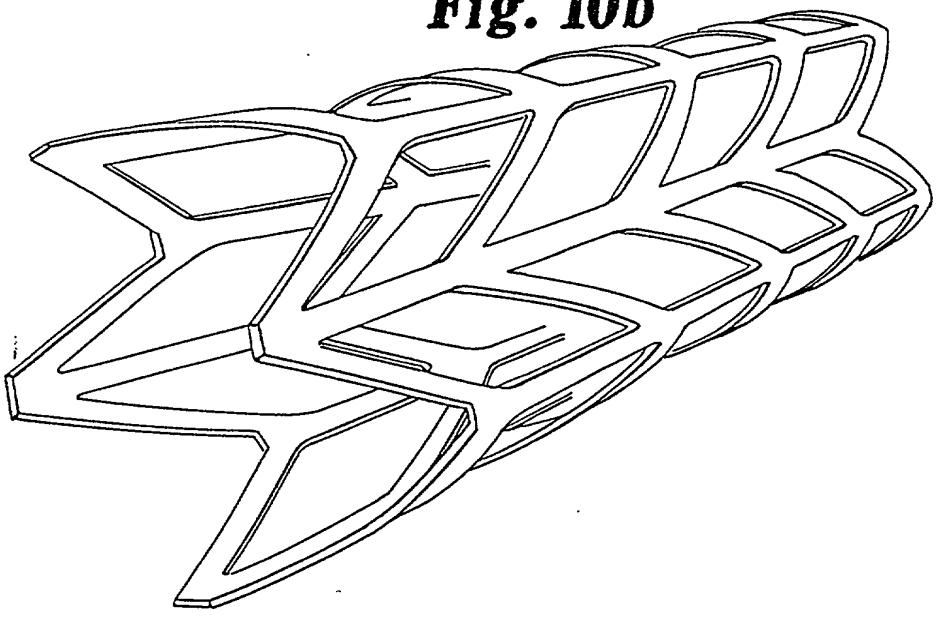


Fig. 10c

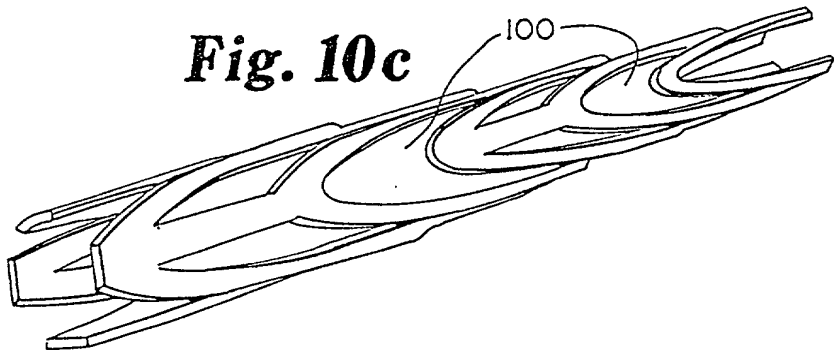


Fig. 10d

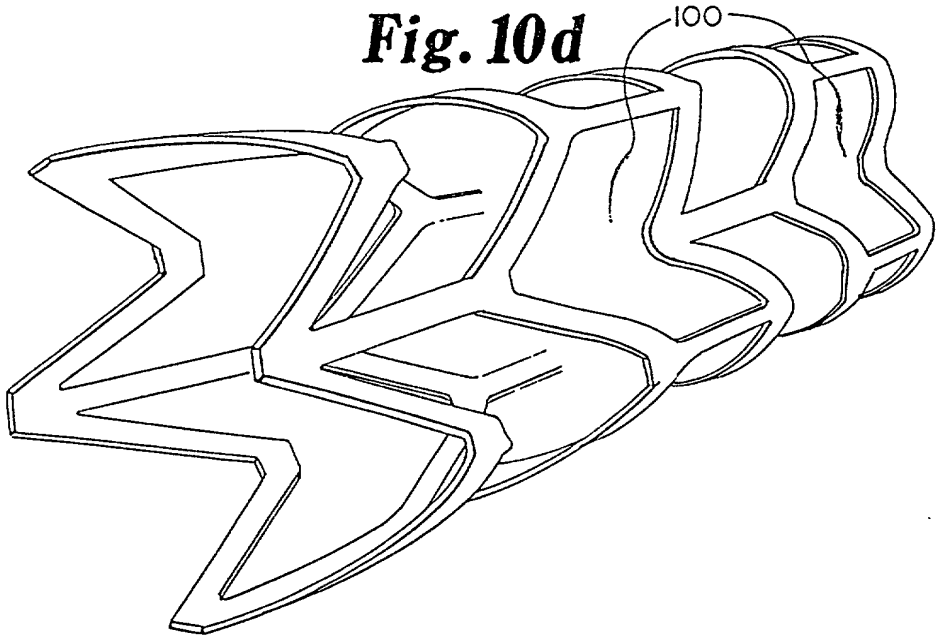


Fig. 11a

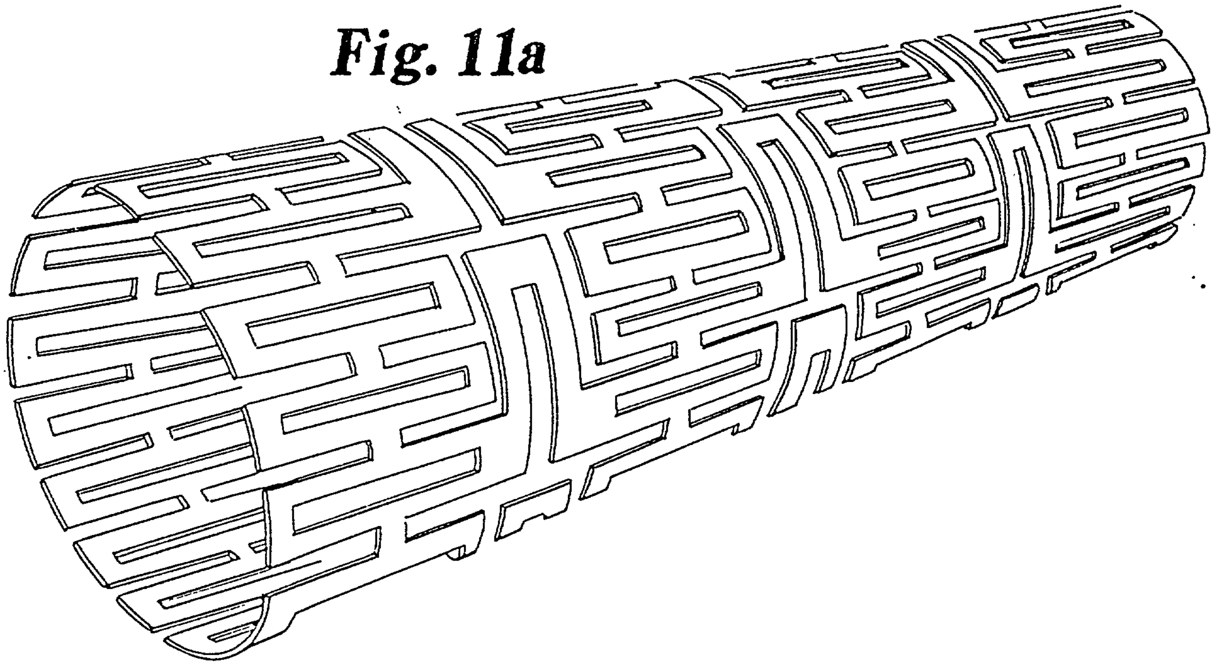


Fig. 11b

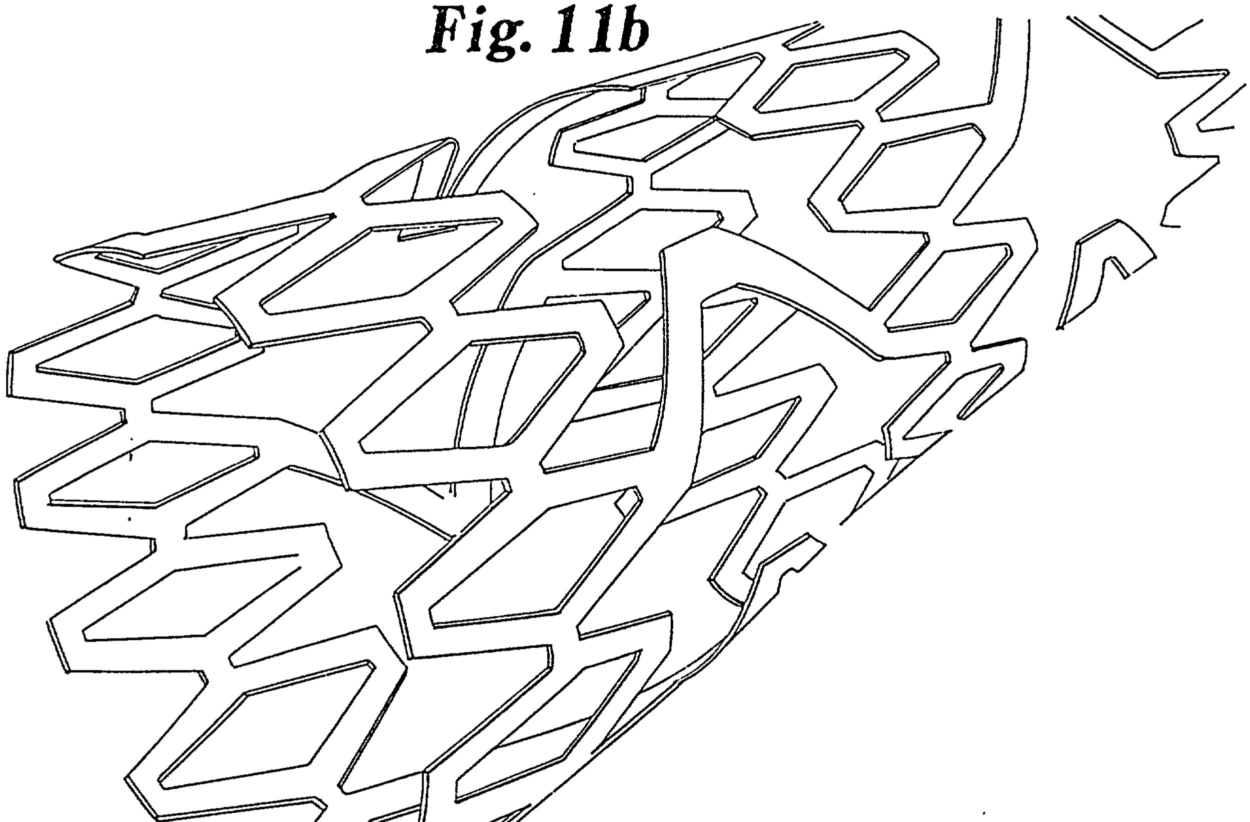


Fig. 12

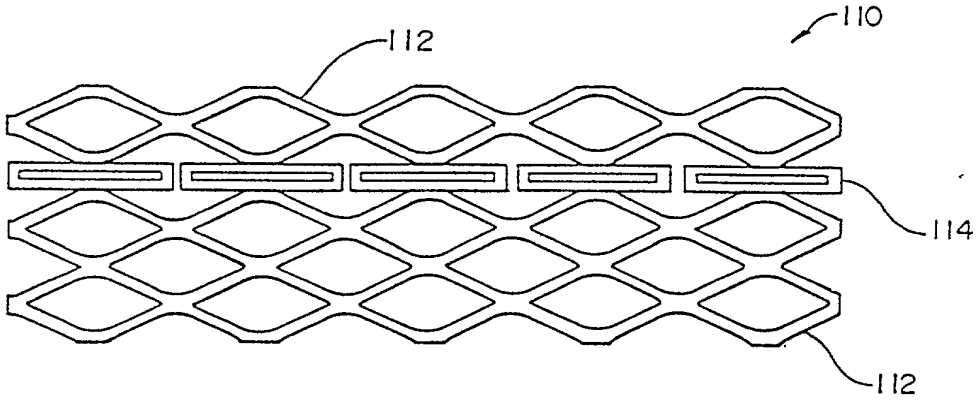


Fig. 13

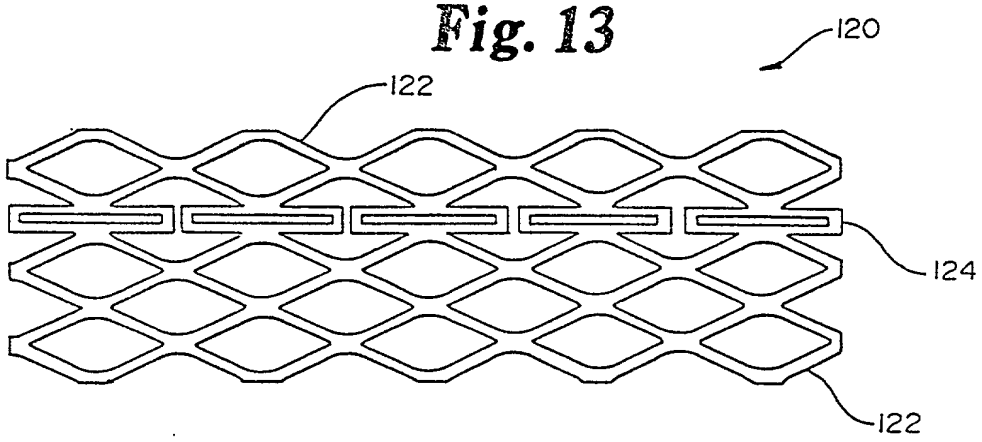


Fig. 14

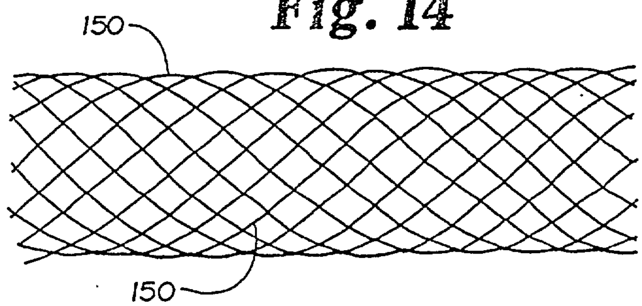


Fig. 15

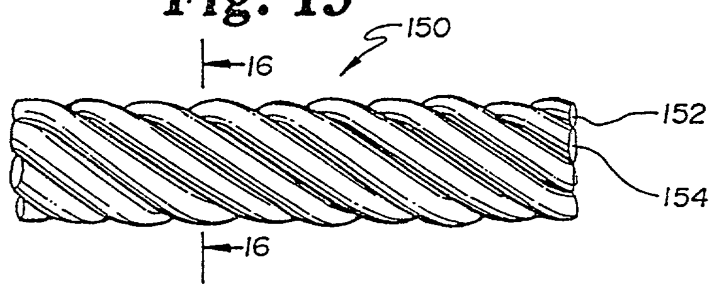
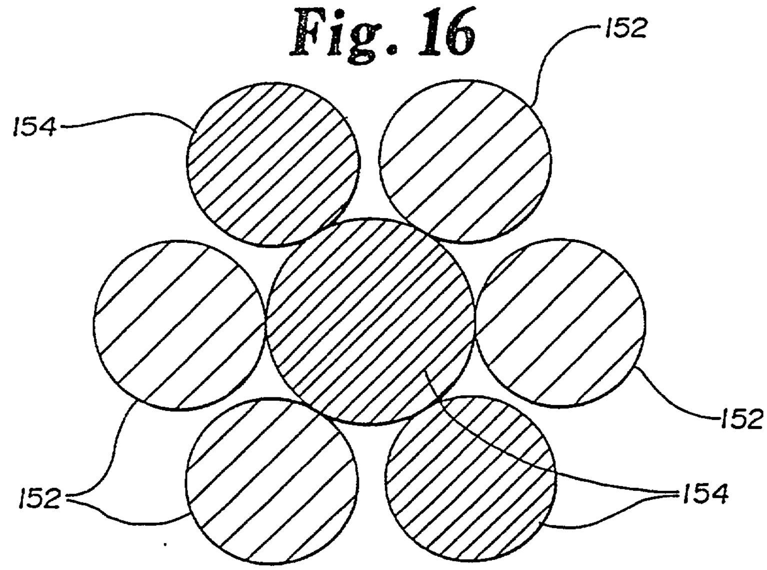


Fig. 16



UTILITY/DESIGN PATENT

Docket No. S63.2-6252

DECLARATION

As a below-named inventor, I(we) hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

- ☐ original
- ☐ design
- ☐ supplemental
- ☒ national stage of PCT
- ☐ divisional
- ☐ continuation
- ☐ continuation-in-part (CIP)

INVENTORSHIP DECLARATION

My residence, post office address, and citizenship are as stated below next to my name;

I verily believe I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter which is claimed and for which a patent is sought on the invention entitled:

IMPROVED TISSUE SUPPORTING DEVICES

the specification of which

- a) ☐ is being filed concurrently herewith
- b) ☐ was filed on_____ and assigned Serial No. _____
- c) ☒ was filed as PCT International Application No. PCT/US95/06228 filed on 18 May 1995 and amended under PCT Article 19 on 26 December 1995 and which has been assigned U.S. Serial No. 08/737,497.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56 including information occurring between the filing date of any prior application of which the present application is a continuation-in-part.

☐ In compliance with this duty there is attached an information disclosure statement. 37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, §119, of any foreign application(s) for patent or inventor's certificate or of any PCT international applications(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT international applications(s) designating at least one country other than the United States of America filed by me having the same subject matter having a filing date before that of the application on which priority is claimed.

EXPRESS MAIL NO.
EM516515924US

a) ☐ no such applications have been filed.
b) ☐ such applications have been filed as follows:

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			☐YES NO☐
			☐YES NO☐

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATIONS(S) UNDER 35 U.S.C. §120

I hereby claim the benefit under Title 35, United States Code, §120 of any United States applications(s) or PCT international applications(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior applications(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior applications(s) and the national or PCT international filing date of this application.

a) ☐ no such applications have been filed.
b) ☒ such applications have been filed as follows.

U.S. APPLICATIONS	
SERIAL NUMBER	U.S. FILING DATE
1. 08/246,320	19 May 1994
2.	
PCT APPLICATIONS DESIGNATING THE U.S.	
PCT APPLICATION NO.	PCT FILING DATE
3.	

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Date:

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Residence:
(If different than above)

Eighth Inventor

Full name:

Inventor's signature:

Date:

Citizenship:

Post office Address:

Residence:
(If different than above)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Paul H. Burmeister et al.
Application No.:	*(Not yet assigned)*
Filed:	October 26, 1999
For:	IMPROVED TISSUE SUPPORTING DEVICES
Examiner:	*(Not yet assigned)*
Group Art Unit:	*(Not yet assigned)*

Assistant Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-8606

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Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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